

Europäisches Patentamt

(19)

European Patent Office

Office européen des brevets



(11)

EP 1 050 274 A1

(12)

EUROPEAN PATENT APPLICATION

published in accordance with Art. 158(3) EPC

(43) Date of publication:

08.11.2000 Bulletin 2000/45

(21) Application number: 99972519.5

(22) Date of filing: 12.10.1999

(51) Int. Cl.: A61B 17/12

(86) International application number:
PCT/JP99/05604

(87) International publication number:
WO 00/30553 (02.06.2000 Gazette 2000/22)

(84) Designated Contracting States:

AT BE CH CY DE DK ES FI FR GB GR IE IT LI LU
MC NL PT SE

(30) Priority: 20.11.1998 JP 33045198

(71) Applicant:

Medical Industries Corporation
Tokyo 113-0034 (JP)

(72) Inventor: SUZUKI, Shigeki

Setagaya-ku, Tokyo 154-0002 (JP)

(74) Representative:

Banzer, Hans-Jörg, Dipl.-Ing.
Kraus & Weisert
Patent- und Rechtsanwälte
Thomas-Wimmer-Ring 15
80539 München (DE)

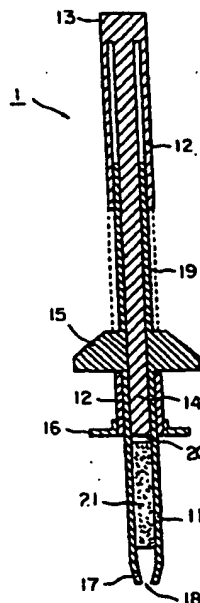
(54) HEMOSTATIC AGENT INSERTING DEVICE

(57) It is a purpose to provide the hemostatic material insertion device for simplifying hemostasis of the puncture wound in the blood vessel, and the method. More concretely, the device comprises the following.

- (a) A cartridge, charged with hemostatic material, which is injected into the puncture foramen
- (b) A hollow sheath which holds said cartridge,
- (c) An ejecting piston portion which forms a one unit with said sheath at the rear end of the sheath and is used for pushing out the hemostatic material charged in said cartridge,
- (d) A guide knob to slide the said cartridge inside the hollow sheath
- (e) A stopping device affixed to the front end of said hollow sheath

Moreover, in this hemostatic material insertion device and the method using the device, the said cartridge, inserted into the puncture foramen through the guide sheath, is slid backwards in the sheath by the guide knob. As a result, it is drawn back out of the puncture foramen, and simultaneously, the puncture foramen is filled with a hemostatic agent charged in the cartridge by means of the ejecting piston in the cartridge, which is united with the said sheath.

FIG. 1



EP 1 050 274 A1

Description

TECHNICAL FIELD

[0001] The present invention relates to a hemostatic material insertion device for sealing a puncture portion in a blood vessel to stop bleeding, as well as the method.

BACKGROUND ART

[0002] In special medical operations, such as a cardiac catheterization, a percutaneous diagnosed contract, a percutaneous transluminal coronary angioplasty (PTCA) or a percutaneous transluminal coronary reconstruction (PTCR), in general, a catheter or other devices are percutaneously inserted into arteries from the inguinal region of the femoral region. After that, they are provided to the operation part, and thereby a low invasive operation is made.

[0003] In order to make the insertion of devices, such as catheters, easier during these operations, the arterial puncture portion must be expanded by a sheath, and followed by appropriate treatments for the completion of the operations. Additionally, after the operations, the sheath must be removed, and the puncture foramen must be closed.

[0004] Provided a puncture foramen is small, the hemostasis could be achieved simply by the application of digital pressure. However, in cases like blood vessel operations, the use of a catheter having a large diameter is much more advantageous, thus an operation is conducted using a sheath with a relatively large diameter.

[0005] However, the digital pressure must be applied for a long time to achieve hemostasis of the puncture foramen after the operation using the sheath with a larger diameter. Consequently, because a patient must be immobilized until the sealing of the puncture foramen is completed, the procedure is painful and uncomfortable for the patient.

[0006] Additionally, it is not easy to seal the foramen perfectly by this procedure, and there is a tendency for the foramen to come open again after it is sealed. Therefore, the patients are required to remain in the hospital for 24 hours or longer.

[0007] Recently, the device, which stops bleeding by filling hemostatic materials, such as collagen, into the puncture foramen, was developed in order to seal the puncture foramen after the insertion of catheter, and the like, by using the sheath with a larger diameter, and the procedure of necessary operations. Thus, the plan of another new device is being proposed, to make it easier sealing a puncture foramen caused by cardiac operations, and the like, which use the sheath with a larger diameter.

[0008] However, the hemostatic devices for puncture foramens, which have been available so far, use

methods that involve pushing and filling a hemostatic material, such as collagen, into the puncture foramen. As a result, an excess hemostatic material can be easily gotten into an arterial canal which is located below the puncture foramen. In order to avoid the filling of the excess hemostatic material, complicated devices are used, which require fairly high skill. Therefore it has been desired to develop a hemostatic material insertion (injection) device more simple and convenient to be used.

DISCLOSURE OF THE INVENTION

[0009] Therefore the purpose of the present invention is to provide the hemostatic material insertion device for sealing a puncture foramen by simple methods to stop bleeding, which does not require complicated devices, and with which filling unnecessarily excess hemostatic materials do not occur. Furthermore, another purpose is to provide the methods for sealing a puncture foramen using thereof.

[0010] As the first fundamental features of the present invention is a hemostatic material insertion device for a puncture foremen comprising;

- (a) A cartridge charged with hemostatic material, which is injected into the puncture foremen,
- (b) A hollow sheath which holds the said cartridge,
- (c) An ejecting piston portion pushing out the hemostatic material charged in the cartridge, which is united with the said sheath at the rear end of the sheath,
- (d) A guide knob to slide the said cartridge inside the hollow sheath, and
- (e) A stopping device equipped on the front end of the said hollow sheath,

and the said cartridge charged with the hemostatic material is inserted into the puncture foremen by adjusting to set to the depth of the puncture foremen by means of the stopping device equipped at the front end of the sheath, then the said cartridge inserted into the puncture foremen is drawn back out of the puncture foremen by backward slide using the guide knob in the sheath, thus filling the puncture foremen with a hemostatic agent charged in the cartridge by means of the ejecting piston in the cartridge, united with the sheath.

[0011] Therefore, the above mentioned hemostatic material injection device of the present invention uses the cartridge which has already been charged with the hemostatic material, so that its insertion into the puncture foremen can be adjusted to its actual depth. Thus one characteristic of this device is that unnecessary excess hemostatic material is not inserted into the inside of an arterial canal located under the puncture foramen.

[0012] For that purpose, in the device of Claim 2, the front tip of the cartridge has a tapered structure. As

a result, the structure makes the insertion into the puncture foramen easier.

[0013] In addition, in the device of Claim 3, the said tapered structure at the tip of the cartridge has been cut, and the filling the hemostatic material, which is charged in the cartridge, into the puncture foramen is also performed easily.

[0014] Based on the first forms mentioned above, the device of Claim 4, which is the second embodiment of the present invention, provides a hollow guide sheath inserted into a puncture foramen. Therefore, it makes the insertion of the cartridge charged with hemostatic material, at the same time it provides that both of the hollow guide sheath and the cartridge are moved synchronously.

[0015] In short, through the hollow guide sheath inserted into a puncture foramen beforehand, the cartridge charged with the hemostatic material is inserted into the puncture foramen. After that, and both of the hollow guide sheath and the cartridge are drawn back out of the puncture foramen by sliding them using the guide knob in the sheath. At the same time, it fills the puncture foramen with the hemostatic agent charged in the cartridge by an ejecting piston in the cartridge.

[0016] A procedure in the hemostatic material insertion device of this invention is characteristic, in which hemostatic material is filled into a puncture foramen. The procedure results from the fact that the hemostatic agent charged in the cartridge are not inserted (filled) by pushing it out *per se*. Instead, it remains inside the puncture foramen accompanying with the movement, in which the cartridge, charged with the hemostatic material that was inserted into it, is drawing out of it. Therefore, by this special characteristic, excess hemostatic material is not filled into the blood vessel under the puncture wound, and hemostasis of the puncture foramen can be accomplished with a high degree of safety.

[0017] Additionally, as another form, the present invention also provides the method for sealing the puncture foramen to stop the bleeding by using the aforementioned hemostatic material insertion device. More definitely, it provides the method to stop bleeding of the puncture foramen by the hemostatic material inserted into the puncture foramen, which has the following characteristics:

First, the cartridge charged with the hemostatic material inserted into the puncture foramen. Next, by sliding the said cartridge, inserted into it, back within a sheath using a guide knob, it is drawn out of the inside of it. At the same time, the hemostatic material, charged in the cartridge within the puncture foramen by means of an ejecting piston inside the cartridge that is united with the sheath, is filled into the puncture foramen wound.

[0018] Furthermore, as additional another form, the present invention provides the method for sealing the puncture foramen to stop the bleeding by using the aforementioned second hemostatic material insertion

device. More concretely, it provides the method to stop bleeding of the puncture foramen by the hemostatic material inserted into the puncture foramen, which has the following characteristics:

First, the cartridge, charged with the hemostatic material by using a hollow sheath, is inserted into the puncture foramen. Second, the both of cartridge and the guide sheath are drawn out of the puncture foramen by sliding them back within the sheath using the guide knob. Simultaneously, the hemostatic material, charged in the cartridge within the puncture foramen, is filled into the puncture foramen wound by means of an ejecting piston inside the cartridge that is united with the sheath.

BRIEF DESCRIPTION OF DRAWINGS

[0019]

FIG. 1 is a vertical section showing the structure for the first performed example of the hemostatic material insertion device of the present invention.

FIGS. 2, 3, and 4 are vertical sections drawing outlines of how to insert the hemostatic material of the present invention into a puncture foramen according to the first performed example.

FIG. 5 is a vertical section showing the structure for the second performed example of a hemostatic material insertion device of the present invention.

FIG. 6 shows the structure of a hollow guide sheath of the second performed example. On the figure, (a) is, a vertical section of the said structure, and (b) is the front view seen from arrow A.

FIG. 7 shows the structure of a cartridge charged with the hemostatic material of the second performed example. On the figure, (a) is the vertical section, and (b) is the front view seen from arrow B. FIG. 8 is an illustration of how to insert a cartridge, charged with the hemostatic material of the second performed example, into a hollow guide sheath, and how to unite them.

FIG. 9 shows the structure for the hollow sheath of the second performed example. On the figure, (a) is the vertical section, (b) is the front view seen from arrow C, and (c) is the front view seen from an opened groove.

FIGS. 10, 11 and 12 are vertical sections showing the outlines of how to fill a puncture foramen with the hemostatic material of the present invention.

Description of the Reference Numerals

[0020]

- | | |
|----|--------------------------------------|
| 1 | Hemostatic material injection device |
| 11 | Cartridge |
| 12 | Hollow sheath |
| 14 | Ejecting piston part |
| 15 | Guide knob |

- 16 Stopping device
- 18 Opened part of tip
- 21 Hemostatic material
- 31 Puncture foramen
- 32 Blood vessel
- 40 Hemostatic material injection device
- 41 Hollow guide sheath
- 42 Cartridge
- 43 Hollow sheath
- 45 Ejecting piston part
- 53 Opened groove

BEST MODE FOR CARRYING OUT THE INVENTION

[0021] As its basic form, as mentioned above, the hemostatic material insertion device of the present invention uses a cartridge which has already been charged with the hemostatic material, and the said cartridge is inserted directly into a puncture foramen, or through a hollow guide sheath. After that, the device leaves the hemostatic material inside the puncture foramen and fills it by means of drawing the cartridge charged with the hemostatic material from the said puncture foramen gradually. In this case, pulling out of the cartridge from the puncture foramen is accomplished by the hollow sheath, which holds the cartridge.

[0022] On the other hand, the insertion of the cartridge, charged with the hemostatic material into the puncture foramen, is adjusted to set it to the depth of the puncture foramen. Consequently, the tip of the cartridge will not be inadvertently inserted into the blood vessel at the lower part of the puncture wound. Such adjustment to set the cartridge insertion to the depth of the puncture foramen is made by the stopping device installed at the front tip of the sheath.

[0023] Furthermore, the following procedure is needed in order to fill the inside of the puncture foramen with the hemostatic material charged in the cartridge by means of drawing out the cartridge charged with the hemostatic material, that is inserted into the puncture foramen. First, the said cartridge is slid back inside the sheath, and simultaneously, the hemostatic material remains in the puncture foramen by the ejecting piston of the cartridge, united with the sheath.

[0024] As a result of the above-mentioned special construction, the hemostatic material insertion device of the present invention has advantages not only simple and convenient, but also preventing inadvertent filling of the hemostatic material into the blood vessel under the puncture wound. Therefore, the use of the hemostatic material insertion device of the present invention possesses special characteristics not found in conventional hemostatic material insertion devices in the point where hemostasis of the puncture foramen can be achieved without requiring high level of skills.

Examples

[0025] The following are more detailed explanations of the hemostatic material insertion device of the present invention referring to the figures.

[0026] FIG.1 shows a vertical section of the hemostatic material insertion device according to the first performed example, which possesses the basic structure for the hemostatic material insertion device of this invention.

[0027] On the figure, the hemostatic material insertion device 1 consists of following parts. The cartridge 11 charged with the hemostatic material 21 which is to be inserted into the puncture foramen, the hollow sheath 12 which holds the aforementioned cartridge, the ejecting piston part 14 which is united with the sheath 12 at the rear end 13 of the said sheath 12, and which pushes out towards the hemostatic material 21, the guide knob 15 which causes the cartridge 11 to slide inside of the hollow sheath 12, and the stopping device 16 equipped at the front tip of the hollow sheath 12.

[0028] The tip portion 17 of the cartridge 11, charged with the hemostatic material 21, has a slightly tapered shape in order to make the insertion into the puncture foramen easier. At the same time, the diameter of the opened tip portion 18, at the tip portion 17 is made slightly narrower than the inside diameter of the cartridge 11. As a result, the charged hemostatic material can be expanded according to its release from the inside of the cartridge 11, and can fill the inside of the puncture foramen compactly when the charged hemostatic material is pushed out by the tip portion 20 of the ejecting piston part 14.

[0029] In this case, it would be acceptable to incise at the tip portion 17 of the cartridge 11 in order to make it easier for the hemostatic material 21 charged in the cartridge to leave from the cartridge and fill the inside of puncture foramen wound.

[0030] On the other hand, there is a stopping device 16 installed at the front tip of the hollow sheath 12 holding the cartridge 11 in order to prevent the insertion of the cartridge any further than the depth of the puncture foramen. For example, such stopping device 16 can be one which slides freely on the outside of the hollow sheath 12, and which adjusts and sets the length of the inserted portion of the cartridge 11, for example, that is like a screw for fixing.

[0031] In the hemostatic material insertion device 1 of this invention, the hemostatic material 21 in the cartridge 11 remains into and fills the inside of the puncture foramen out of the opened tip 8 of the cartridge 11. This results from the movement of the front end 20 of the ejecting piston part 14 which is united with the hollow sheath by means of sliding the cartridge backwards inside the hollow sheath 12. However, in order to slide the cartridge 11 inside the hollow sheath 12, the guide knob 15 is installed on the cartridge 11. In addition, for example, the opened groove 19 is constructed for the

free movement of this guide knob 15 on the both sides of the hollow sheath 12, and the structure is used in which the guide knob inside the opened groove 19. Consequently, the guide knob 15 can be accomplished. Therefore, the possible distance, for the backward slide of the guide knob 15 within the opened groove 19, is sufficient as long as the length for the insertion of the cartridge 11 into the puncture foramen at least.

[0032] In the hemostatic material insertion device of the present invention, the cartridge 11 is slid backwards inside of the hollow sheath 12 which holds the cartridge 11 charged with the hemostatic material 21. Regarding the distance that makes the backward slide possible for this case, it is also sufficient as long as the insertion length of the cartridge 11 at least.

[0033] Additionally, the hemostatic material 21, in the cartridge 11, is charged close to the front end 20 of the ejecting piston part 14 equipped inside of the cartridge 11. Therefore, following the cartridge's backward slide inside of the hollow sheath 12, the ejecting piston part 14 is united and fixed to the said hollow sheath. Consequently, the hemostatic material, 21 is pushed out of the cartridge's inside, and remains in and fills the inside of the puncture foramen.

[0034] The following explains the concrete method of the insertion of the hemostatic material into the puncture foramen by using the hemostatic material insertion device according to the first performed example of this invention, as described.

[0035] First of all, in cardiac catheter surgeries using large diameter sheaths, such as percutaneous transluminal coronary angioplasty (PTCA) or percutaneous transluminal coronary reconstruction (PTCR), adjust the length of the insertion part of the cartridge 11 charged with the hemostatic material by the stopping device equipped at the front end of the hollow sheath. By the procedure, when the surgeries are finished, the length of becomes the same as the depth of the puncture foramen after the sheath is removed.

[0036] Then, as shown in FIG. 2, insert the device inside the puncture foramen 31 located on the skin surface 30. In this condition, regarding the insertion of the cartridge 11 inside the puncture foramen the hemostatic material injection device 1 is fixed on the skin surface 30 by means of the stopping device 16, which is adjusted to the depth of the puncture foramen. Consequently, the tip portion 17 of the cartridge 11 is never inserted into the blood vessel 32 located below the puncture wound.

[0037] Then, as shown in FIG. 3, maintaining this condition with the stopping device fixed on the skin surface 30, slide the cartridge 11 inserted in the puncture foramen 31 backwards (shown by an arrow in FIG. 3) by the guide knob 15 in the hollow sheath 12.

[0038] By the backward slide of the cartridge 11, the cartridge is drawn out from the puncture foramen 31. Simultaneously, the hemostatic material 21 in the cartridge 11 is pushed out of the opened tip 18 of the cartridge 11 by the movement of the front end 20 of the

ejecting piston part 14. Additionally, since the inner diameter of the opened tip 18 is slightly narrower than that of the cartridge 11, it begins to expand inside the puncture foramen as released, and both remains and is filled in the puncture foramen compactly.

[0039] When the cartridge 11 is completely pulled out from the puncture foramen, as shown in FIG. 4, the hemostatic material 21 is inserted compactly into the puncture foramen 31. Simultaneously, the device 1 is removed, and the insertion of the hemostatic material 21 into the puncture foramen is completed.

[0040] FIG. 5 shows a vertical section of the second performed example of the hemostatic material insertion device.

[0041] In the figure, the hemostatic material insertion device 40 comprises of the following. A hollow guide sheath 41 inserted into the puncture foramen, a cartridge 42 charged with the hemostatic material 21, which is inserted into the said hollow guide sheath 41, a hollow sheath 43 maintaining the aforementioned cartridge, a ejecting piston 45 pushing out the hemostatic material 21 in the cartridge 42 which is united with the hollow sheath 43 at the rear end 44 of said sheath 43, a guide knobs 46 and 47 which cause both of the cartridge 42 and the guide sheath 41 to slide inside of the hollow sheath 43, and a stopping fixture 48 equipped at the front tip of the hollow sheath 43.

[0042] In the second performed example, the insertion of the hemostatic material, which is charged in the cartridge 42, into the puncture foramen is performed in the same way as the first one. In short, the hemostatic material 21 in the cartridge 42 remains in and fills inside of the puncture foramen. This is caused by the front end 49 of the ejecting piston 45, which is united with the said hollow sheath by means of sliding backwards said cartridge 42 inside of the hollow sheath 43.

[0043] On the other hand, in the second performed example, the followings are different from the first embodiment of the device. That is, in order to simplify the insertion of the cartridge 43 charged with the hemostatic material into the puncture foramen, the cartridge 43 is inserted through the hollow guide sheath 41. Then, the both of the hollow guide sheath 41 and the cartridge are united, and slid backwards inside of the sheath 43 using the guide knobs 46 and 47.

[0044] FIG. 6 shows the vertical section of the hollow guide sheath 41, and FIG. 7 shows the vertical section of the cartridge 42 charged with the hemostatic material, which is inserted into the said guide sheath 41.

[0045] Moreover, seen from the figures, the hollow guide sheath 41 used in the second performed example has a length and a diameter in order to insert into the puncture foramen, and a pipe-shape in which the cartridge 42 can be inserted. Furthermore, the guide knob 47 is equipped at the end of the guide sheath, and in the guide knob 47, the groove 51 is equipped, in which the guide knob can be inserted in order to unite with the cartridge inside the guide sheath. The FIG. 6 (b) shows the

shape of the guide sheath shown in the FIG. 6 (a) from the view of the arrow A.

[0046] On the other hand, the cartridge 42 charged with the hemostatic material, which is put into the hollow guide sheath, has a diameter to be inserted into the guide sheath 41. In addition, the guide knob 46, which is able to put into the groove 51 equipped in the knob 47 of the guide sheath 41, is provided at the end of said cartridge. The FIG. 7 (b) shows the shape of the cartridge 42 shown in the FIG. 6 (a) from the view of the guide knob 46 by the arrow B.

[0047] The length of the guide sheath 41 coincides with that of the cartridge 42 at the ends, and the lengths, enough to be inserted, are appropriate.

[0048] FIG. 8 (a) and (b) shows the state where the cartridge 42, charged with the hemostatic material, is united with the hollow guide sheath 41. In other words, the cartridge 42 is put inside the hollow sheath inserted into the puncture foramen (directed by the arrow in FIG. 8 (a)). Furthermore, the knob 46 of the cartridge 42 is put into the groove 51 equipped on the guide knob 47 of the sheath 41. As a result, the both of them are united.

[0049] United in such a way, the both of the sheath 41 and the cartridge 42 charged with the hemostatic material 21 are slid backwards in the hollow sheath 43. As a result, the hemostatic material 21 in the cartridge 42 is injected into the puncture foramen by means of the ejecting piston. The FIG. 9 shows the vertical section of the cartridge 43.

[0050] From the figure, the front end of the hollow sheath 43 has the stopping device 48 against the skin surface, and also has the opening part 52 to put the cartridge 42 (and the guide sheath 41 in one unit) into the hollow sheath 43. On the other hand, at its rear end 44, there is the ejecting piston 45 united with the said hollow sheath 43, which pushes out the hemostatic material 22 in the cartridge 42. Furthermore, the said sheath 43 has the opening groove 53 at the both sides, which is necessary for sliding the cartridge 42 (and the guide sheath 41 in one unit) backwards inside of the sheath 43. In addition, the movement of the cartridge is performed by the structure sliding the guide knobs 46 and 47 through the opening groove 53. Therefore, the possible length for the backward slides of these guide knobs in the opening groove 53 may be an enough length, which is proportionate to the insertion length of the cartridge 42 (and the guide sheath 41) into the puncture foramen. Moreover, the FIG. 9 (b) shows the opening groove 52 of the hollow sheath 43 from the view of the arrow C in the FIG. 9 (c), and the FIG. 9 (b) shows the front view of the opening groove 53 of the hollow sheath 43.

[0051] The following is an explanation of the concrete method of the insertion, into the puncture foramen of the hemostatic material by using the hemostatic material insertion device according to the second performed example of the invention, as described above.

[0052] First, as shown in the FIG. 10, after a surgery using a large diameter sheath, such as percutane-

ous transluminal coronary angioplasty (PTCA) or percutaneous transluminal coronary reconstruction (PTCR), the guide hollow sheath 41 is inserted into the puncture foramen so as to correspond the insertion length to the depth of the puncture foramen after the sheath's removal. Then, the cartridge 42 charged with the hemostatic material is put into the said guide sheath 41 from the front side of the cartridge 42. Simultaneously, the both of the guide sheath 41 and the cartridge 42 are united by means of getting the knob 46 into the knob 47.

[0053] In this condition, as shown in the FIG. 11, the insertion of the cartridge 42 into the puncture foramen is easily accomplished through the guide sheath 41. At the same time, this hemostatic material insertion device is fixed on the skin surface 30 by means of the stopping device 48 equipped at the front tip of the hollow sheath 43. As a result, the front tip 50 of the cartridge 42 is never inserted into the blood vessel 32 below the puncture wound.

[0054] Then, maintain this position with the stopping device fixed on the skin surface 30. In this condition, slide the cartridge 42 (and the guide sheath 41 in one unit) inserted in the puncture foramen 31 backwards (directed by the arrow in FIG. 11) by using the guide knob 46 (and the knob 47 in one unit) in the opening groove 53 inside of the hollow sheath 43.

[0055] By sliding the cartridge 42 (and the guide sheath 41 in one unit) backwards, the cartridge 42 is drawn out from the puncture foramen 31 with the guide sheath 41 in one unit. Simultaneously, the hemostatic material 21 in the cartridge 42 gets pushed out from the front opening part 50 of the cartridge by the action of the front end 49 of the ejecting piston 45, and remains and accumulates compactly.

[0056] As shown in FIG. 12, when the cartridge 42 (and the guide sheath 41 in one unit) is completely pulled out from the puncture foramen, the hemostatic material 21 is inserted compactly into the puncture foramen 31. At the same time, the device is removed and the inserting of the hemostatic material 21 into the puncture foramen is completed.

[0057] In addition, as long as it possesses the basic construction described above, the hemostatic material insertion device of the present invention includes various modifications, and all of these would all be included within the scope of this invention.

[0058] By the above-mentioned procedures, the hemostatic material can be easily inserted into the puncture foramen. The examples of hemostatic materials include collagen, which is conventionally used for various hemostatic purposes, or soluble hemostatic cellulose. Especially, it became clear that soluble hemostatic cellulose produces good results as a hemostatic material for this injection device.

[0059] It is possible to install a guide wire into the center of the hemostatic agent insertion device of the present invention in order to assure the insertion of the

cartridge inside the puncture foramen. However, such a guide wire is not always necessarily. Particularly, in consideration of the fact that hemostatic procedures for the puncture foramen are done immediately following the removal of the sheath after a surgery, the insertion of the cartridge into the puncture foramen would be possible without it.

[0060] Of course, the hemostatic material insertion device of the present invention could be applied not only for hemostasis of the puncture foramen of blood vessels as described above, but also for hemostasis of body cavity surgeries.

INDUSTRIAL APPLICABILITY

[0061] As stated above, compared to hemostatic methods using the complicated conventional devices, the hemostatic agent insertion device of the present invention makes it easier to insert the hemostatic material into the puncture foramen. Furthermore, the risk of inadvertent injection of the hemostatic material into the blood vessel at the bottom of the puncture foramen is avoided due to the fact that the length of the cartridge, inserted into the puncture foramen can be adjusted freely according to the depth of the puncture foramen. In this point, the safety and superiority of this hemostasis material injection can be understood.

[0062] In addition, the hemostatic material is inserted by pulling out the cartridge charged with it from the inside of the puncture foramen. For this reason, compared to the conventional insertion, it does not require technical of skills, consequently, the medical application is higher.

Claims

1. A hemostatic material insertion device for a puncture foramen comprising

- (f) A cartridge charged with hemostatic material, which is injected into the puncture foramen,
- (g) A hollow sheath which holds the said cartridge,
- (h) An ejecting piston portion pushing out the hemostatic material charged in the cartridge; which is united with the said sheath at the rear end of the sheath,
- (i) A guide knob to slide the said cartridge inside the hollow sheath, and
- (j) A stopping device equipped on the front end of the said hollow sheath,

and the said cartridge charged with the hemostatic material is inserted into the puncture foramen by adjusting to set to the depth of the puncture foramen by means of the stopping device equipped at the front end of the sheath, then the said cartridge

inserted into the puncture foramen is drawn back out of the puncture foramen by backward slide using the guide knob in the sheath, thus filling the puncture foramen with a hemostatic agent charged in the cartridge by means of the ejecting piston in the cartridge, united with the sheath.

2. The hemostatic material insertion device claimed in Claim 1, wherein the tip portion of the said cartridge has a tapered structure.
3. The hemostatic material insertion device claimed in Claim 2, wherein a cut is made in the said tapered portion.
4. The hemostatic material insertion device claimed any one of Claim 1 to 3 wherein the guide sheath is used for the insertion of the cartridge charged with the hemostatic material into the puncture foramen, and the guide sheath and the cartridge are united.
5. The hemostatic material insertion device claimed in Claim 1, wherein the hemostatic materials are collagen or soluble hemostatic cellulose.
6. The method for stopping bleeding of a puncture foramen has following characteristics by the insertion of the hemostatic agent into the puncture foramen, wherein the cartridge charged with the hemostatic material is inserted into the puncture foramen for sealing it; simultaneously, it is pulled out of the puncture foramen by sliding the said inserted cartridge backward by a guide knob inside a sheath, and the puncture wound is filled with the hemostatic agent charged in the cartridge into the puncture foramen by means of an ejecting piston part, united with the sheath inside the cartridge, at the same time.
7. The method for stopping bleeding of the puncture foramen claimed in Claim 6, wherein the insertion of the cartridge, charged with the hemostatic material, into the puncture foramen is carried out through a guide sheath.
8. The method for stopping bleeding of the puncture foramen claimed in Claim 6 or 7, wherein the hemostatic materials are collagen or soluble hemostatic cellulose.
9. The hemostatic material insertion device claimed in any one of Claim 1 to 5, which is to be utilized in the method for stopping bleeding of the puncture wounds as described in Claims 6 or 7.

FIG. 1

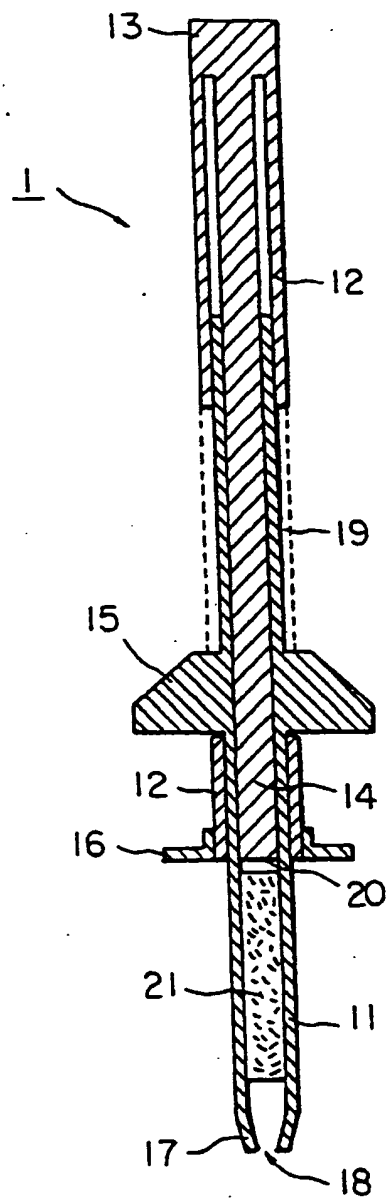




FIG. 3

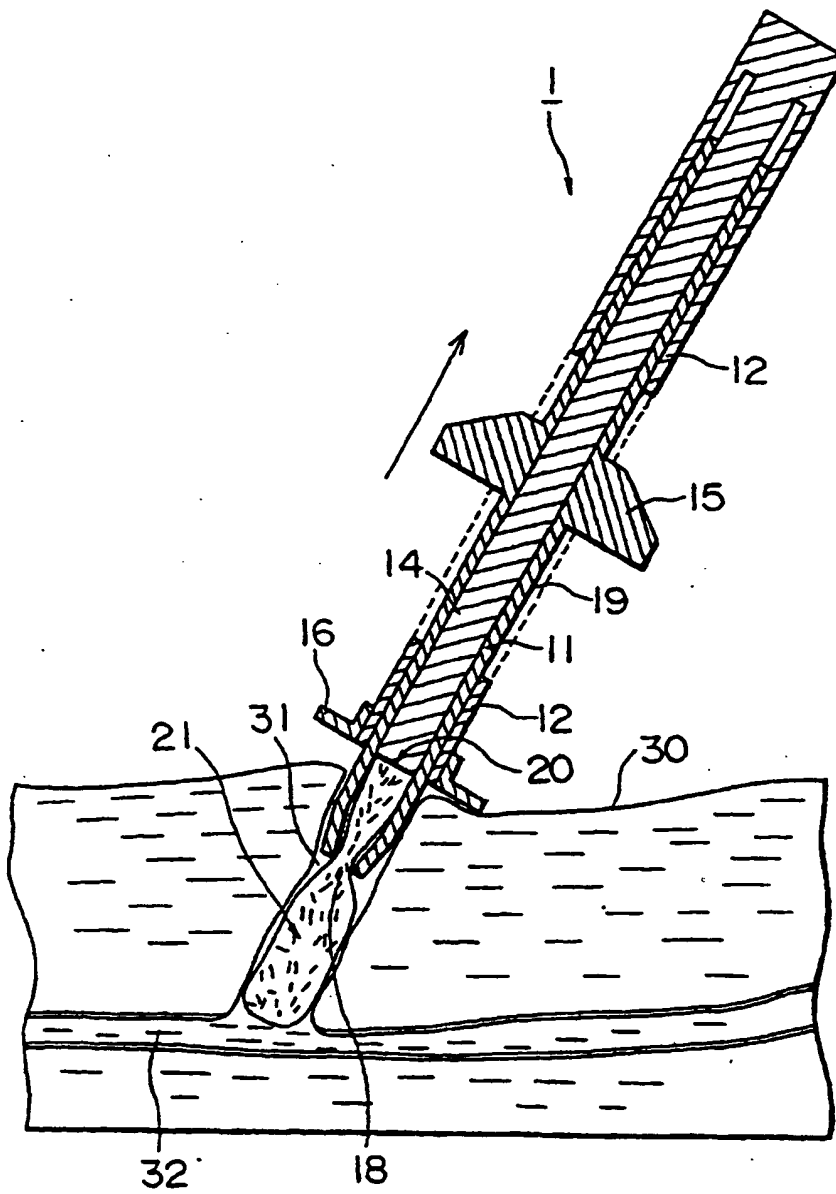


FIG. 4

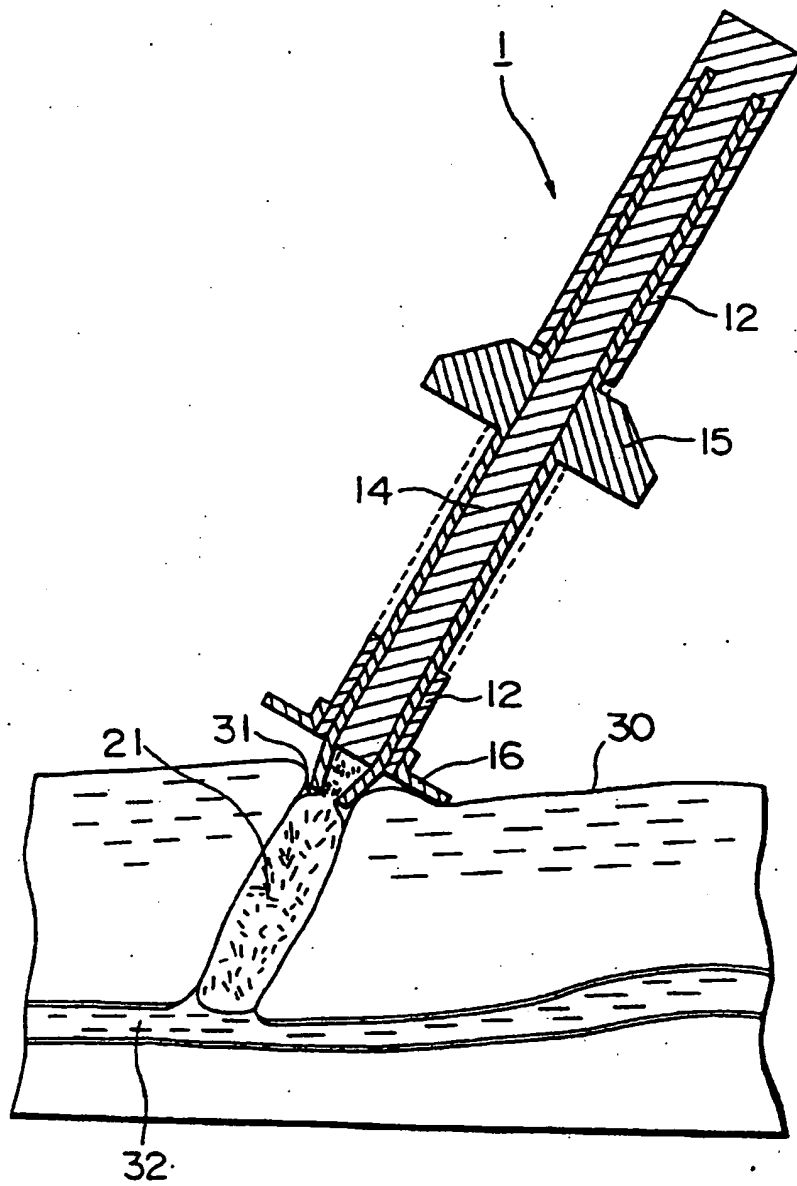


FIG. 5

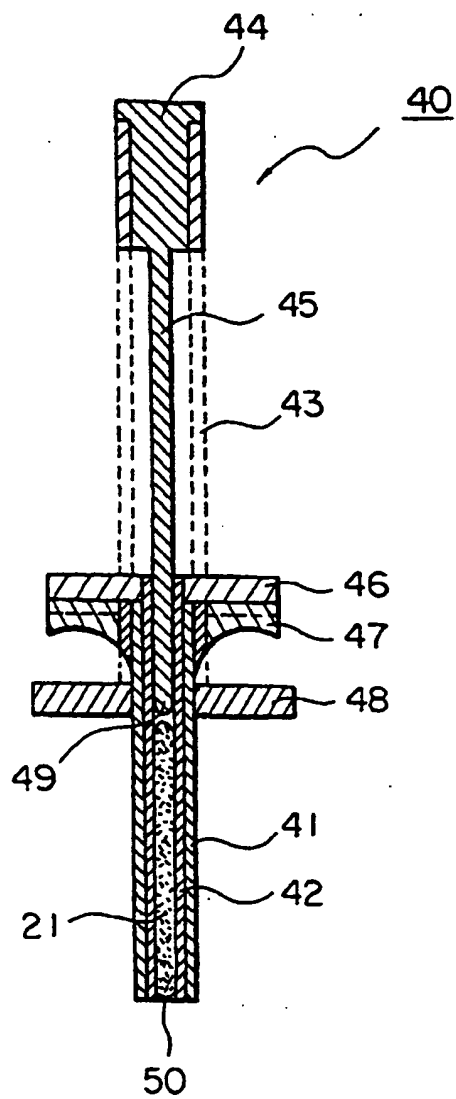


FIG. 6A

FIG. 6B

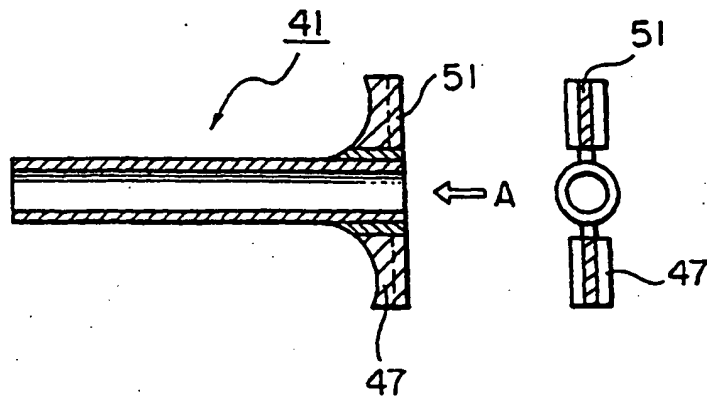


FIG. 7A

FIG. 7B

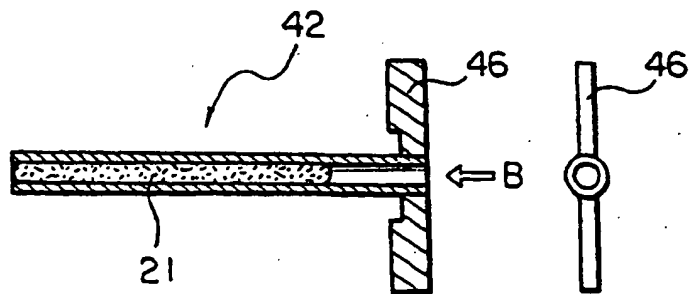


FIG. 8A

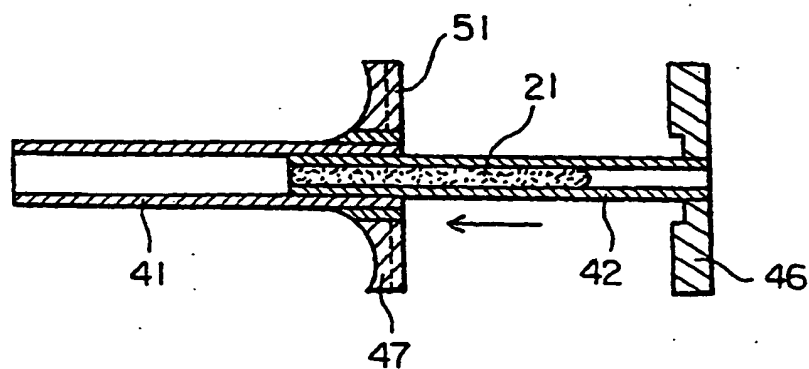


FIG. 8B

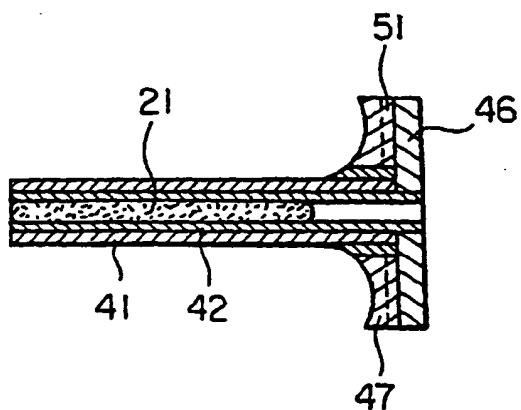


FIG. 9A

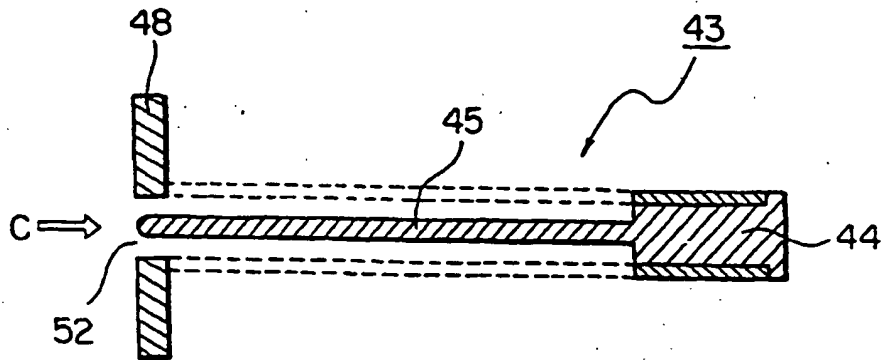


FIG. 9B

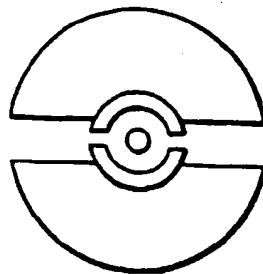


FIG. 9C

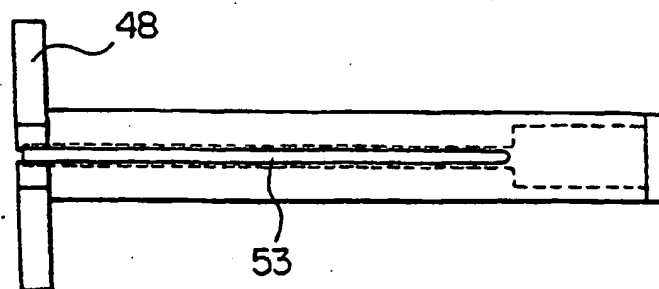


FIG. 10

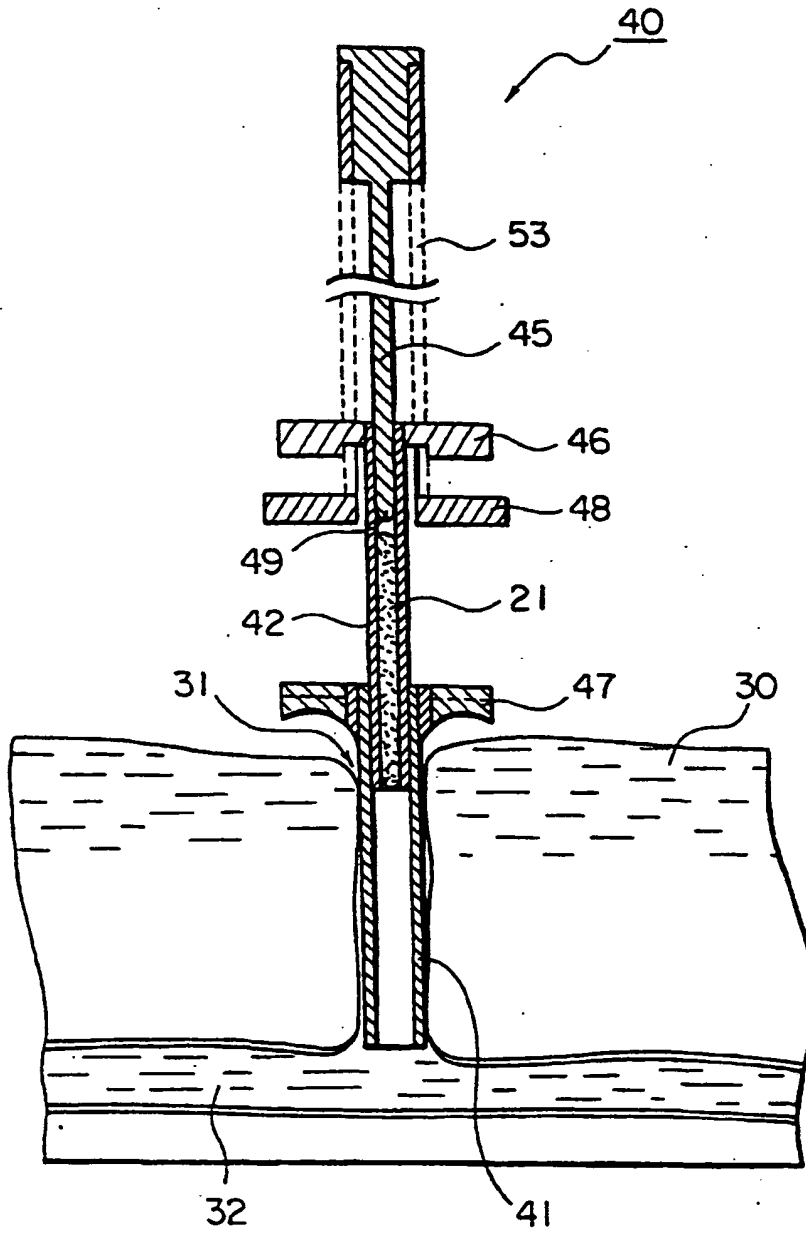


FIG. 11

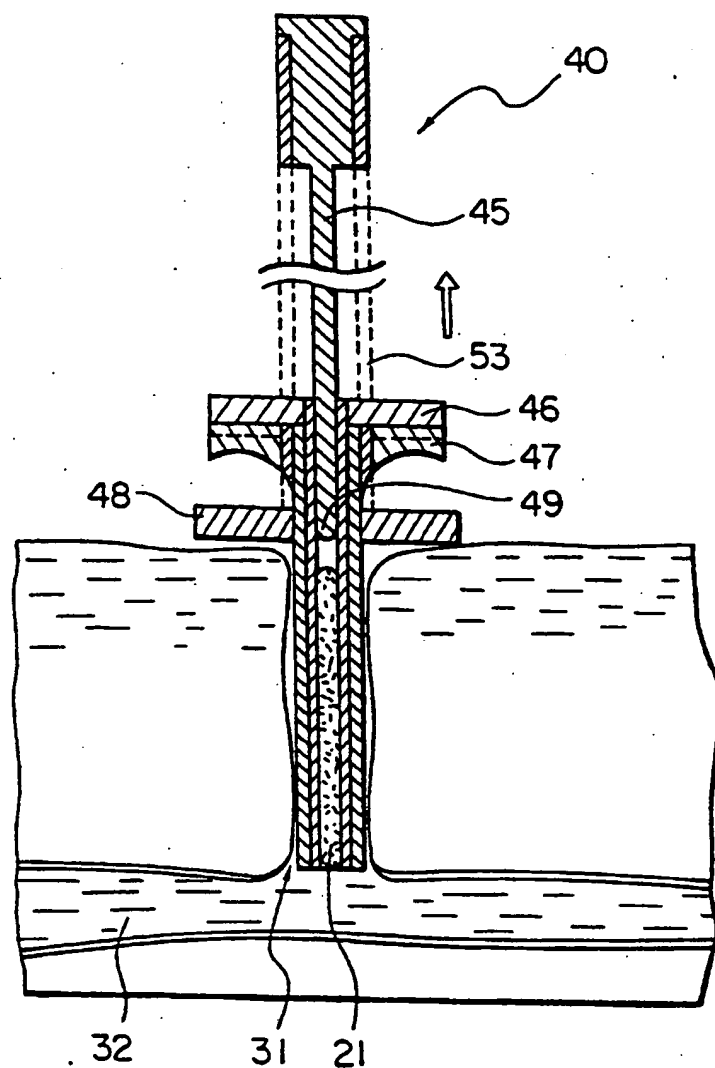
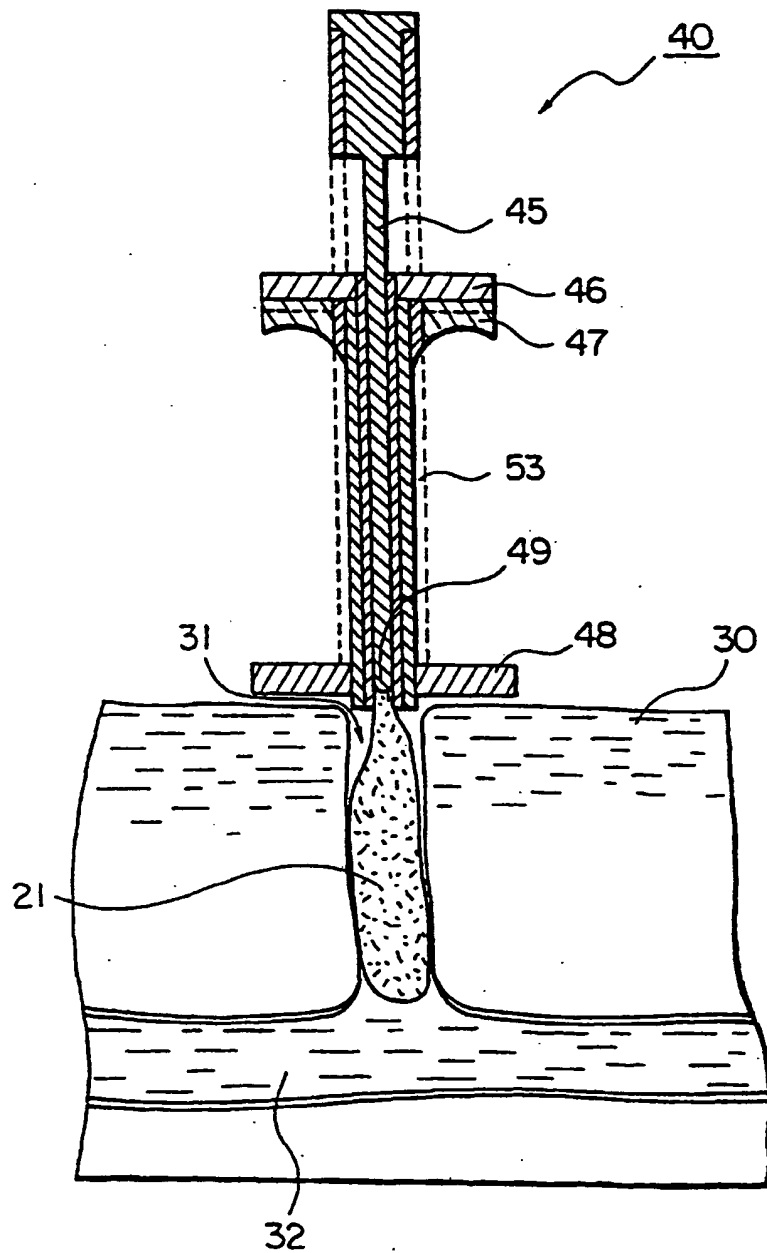


FIG. 12



INTERNATIONAL SEARCH REPORT

International application No.

PCT/JP99/05604

A. CLASSIFICATION OF SUBJECT MATTER

Int.Cl.⁶ A61B17/12, A61M5/18, A61M37/00

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

Int.Cl.⁶ A61B17/00-17/12, 5/00-37/00

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Jitsuyo Shinan Koho	1926-1996	Toroku Jitsuyo Shinan Koho	1994-1999
Kokai Jitsuyo Shinan Koho	1971-1995	Jitsuyo Shinan Toroku Koho	1996-1999

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	JP, 9-504444, A (Boston Scientific Corporation), 06 May, 1997 (06.05.97), Full text; Fig. 6	6
Y	& WO, 95/05206, A1	7-8
A		1-5, 9
X	JP, 10-504745, A (Kenney Nash Corporation), 12 May, 1998 (12.05.98), Full text; Figs. 9, 10	6, 8
Y	& WO, 96/05772, A1	7
A		1-5, 9
Y	JP, 9-505233, A (Sherwood Medical Company), 27 May, 1997 (27.05.97), Full text; Figs. 1-8	7
	& WO, 96/24290, A1	
Y	JP, 6-339483, A (Datascope Investment Corporation), 13 December, 1994 (13.12.94), page 9, right column, lines 9-16; Fig. 12	8
	& EP, 476178, A1 & US, 5391183, A	
Y	JP, 7-506513, A (HAGA, John, R.), 20 July, 1995 (20.07.95),	8

☒ Further documents are listed in the continuation of Box C.☐ See patent family annex.

* Special categories of cited documents:

"A" document defining the general state of the art which is not

considered to be of particular relevance

"E" earlier document but published on or after the international filing

date

"L" document which may throw doubts on priority claim(s) or which is

cited to establish the publication date of another citation or other

special reasons (as specified)

"O" document referring to an oral disclosure, use, exhibition or other

means

"P" document published prior to the international filing date but later

than the priority date claimed

"T" later documents published after the international filing date or

priority date and not in conflict with the application but cited to

understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be

considered novel or cannot be considered to involve an inventive

step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be

considered to involve an inventive step when the document is

combined with one or more other such documents, such

combination being obvious to a person skilled in the art

"A" document member of the same patent family

Date of the actual completion of the international search
27 October, 1999 (27.10.99)Date of mailing of the international search report
09 November, 1999 (09.11.99)Name and mailing address of the ISA/
Japanese Patent Office

Authorized officer

Facsimile No.

Telephone No.

Form PCT/ISA/210 (second sheet) (July 1992)

EP 1 050 274 A1

INTERNATIONAL SEARCH REPORT

International application No.

PCT/JP99/05604

C (Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
	<p>page 7, upper left column, lines 19-21 & NO. 93/25255, A1</p>	

Form PCT/ISA/210 (continuation of second sheet) (July 1992)